Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 5, 6, 8, 10, 12, 14, 16 and 26-30 are pending in this application, with claims 5, 6, 8, 10, 12 and 14 being the independent claims. Claims 5, 6, 8, 10, 12, 14, 16 and 26-30 have been amended to clarify the claimed invention. These changes are believed to introduce no new matter, and their entry is respectfully requested. Support for the amendments to the claims can be found, *inter alia*, in the claims as originally filed. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Objections to the Claims

The Examiner has objected to claims 5, 6, 8, 10, 12, 14, 16 and 26-30 because "the claims should be crafted to provide more clarity." (Office Action, Page 2.) Applicants have rewritten claims 5, 6, 8, 12, 14, 16, and 26-30 to provide more clarity in accordance with the Examiner's suggestions. For example claim 5 now recites "[a] peptide comprising an amino acid sequence from 9 to 12 amino acids in length selected from the group consisting of . . . wherein said amino acid sequence is derived from protein E6 or E7 of HPV16; and wherein said peptide has the ability to bind to human MHC Class I allele HLA-A2.1." Furthermore, claims 26-30 have been amended so that each, respectively, corresponds to a pharmaceutical composition comprising the claimed

peptide and a pharmaceutically acceptable carrier. For example, claim 16 now recites "[a] pharmaceutical composition comprising the peptide of claim 5 and a pharmaceutically acceptable carrier, diluent, excipient or adjuvant." Finally, claims 27-30 have been amended to recite "pharmaceutically acceptable carrier." Therefore, the objection with regard to claims 5, 6, 8, 12, 14, 16 and 26-30 has been rendered moot. Accordingly, Applicants respectfully request that this objection be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 112

The Examiner has rejected claims 5, 6, 8, 10, 12, 14, 16 and 26-30 under 35 U.S.C. § 112, first paragraph, for lack of enablement. (Office Action, Page 3.) In particular, the Examiner states that the "rejection is maintained because there are claims pending directed to a pharmaceutical composition." (*Id.*) The Examiner alleges that "the specification does not teach how to use the claimed pharmaceutical composition in the treatment of HPV16- and/or HPV18-induced diseases comprising administering the pharmaceutical composition to a subject" and that "to enable a pharmaceutical use for a substance, the specification must teach how to use the substance, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure a disease in the animal or subject to which the substance is administered." (Office Action, Page 4.) Applicants respectfully disagree and traverse the rejection.

As an initial matter, Applicants note that none of claims 5, 6, 8, 10, 12 or 14 are directed to pharmaceuticals compositions or recite the term "pharmaceutical." Each of claims 5, 6, 8, 10, 12 and 14 are directed to an *isolated peptide*. Accordingly, the

Examiner's rejection under 35 U.S.C. § 112, first paragraph, for lack of enablement, does not apply to these claims. Applicants respectfully request that this rejection with respect to claims 5, 6, 8, 10, 12 and 14 be reconsidered and withdrawn.

In addition, Applicants assert that the rejection of claims 16 and 26-30 under 35 U.S.C. § 112, first paragraph, for lack of enablement, is improper as there *is no use limitation recited in these claims.* Claims 16 and 26-30 are directed to a type of composition, a "pharmaceutical composition." The claims do not further recite any limitation related to the administration of the composition, nor do the claims recite any limitation related to the use of the claimed peptide in the prevention, diagnosis, alleviation, treatment or cure of a disease. As described in the specification, "[t]he novel peptides of the present invention are useful in pharmaceutical compositions, as screening tools . . . ." (Specification, Page 4, lines 12-16.) As such, the term "pharmaceutical composition" does not denote that these compositions are necessarily for therapeutic use.

Claims 16 and 26-30, directed to a pharmaceutical composition with no further recitation of a therapeutic use, therefore, cannot be rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Applicants assert that the Examiner has improperly read such a use limitation into claims 16 and 26-30, and therefore a rejection of these claims under 35 U.S.C. § 112, first paragraph, for lack of enablement is improper. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 10, 12, 28 and 29 under 35 U.S.C. § 102(b) as being anticipated by Tindle et al. (PNAS, July 1991, 88:5887-5891) ("Tindle"). (Office Action, Page 8.) In particular, the Examiner notes that the "B2 peptide disclosed in Table 1 is the same claimed SEQ ID NO:59." (*Id.*)

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). MPEP § 2131. Applicants have amended claims 10 and 12 to exclude the peptide corresponding to SEQ ID NO:59 from the claims. Tindle does not anticipate claims 10, 12, 28 and 29 as amended. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

In addition, the Examiner has rejected claims 5 and 16 under 35 U.S.C. § 102(b) as being anticipated by Comerford et al. (J. Virology, Sept. 1991, 65/9:4681-4690) ("Comerford"). (Office Action, Page 9.) In particular, the Examiner notes that the "Comerford et al discloses the peptide sequence of EYMLDLQPETT, which is 12 amino acids in length and discloses claimed SEQ ID NO:14 (EYMLDLQPETT)." (Office Action, Page 10.) Applicants note that SEQ ID NO:14 does not correspond to the sequence EYMLDLQPETT. Rather SEQ ID NO:14 corresponds to YMLDLQPET.

However, without acquiescing to the propriety of the rejection and in efforts to advance prosecution, Applicants have amended claim 5 to exclude the peptide corresponding to SEQ ID NO:14 from the claims. Applicants reserve the right to pursue

claims directed to the subject matter of SEQ ID NO:14 in continuing or divisional applications.

Because claim 5 no longer recites the peptide corresponding to SEQ ID NO:14, Applicants assert that current claims 5 and 16 are not anticipated by Comerford. Comerford therefore does not disclose each and every limitation of the claimed invention. In addition, none of the peptides recited in the pending claims as amended are disclosed in Tindle or Comerford. Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Mita Mukherjee
Agent for Applicants
Registration No. 54,325

Date: November 20, 2006

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

609859_1.DOC